

REMARKS

Claims 1-20 are currently pending in this application. Claims 2 and 9-15 have been canceled in this amendment, without admission and without prejudice to Applicant's right to pursue the subject matter of those canceled claims in either this or other (e.g., related divisionals and other continuing) applications. Previously present claims 1, 3-8 and 16-20 will remain pending upon the entry of this amendment. Hence, no new matter has been introduced. The entry and consideration of this amendment is therefore respectfully requested.

A. The Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 2 and 9-15 have been rejected under the first paragraph of 35 U.S.C. § 112, as failing to comply with the written description requirement of that statute. Applicant respectfully traverses this rejection for the reasons set forth in the previous communication filed July 3, 2008. Nevertheless, the rejected claims have been canceled without prejudice or admission in order to expedite an allowance and/or to reduce issues for appeal. The withdrawal of this rejection is therefore respectfully requested.

B. The Prior Art Rejections Should Be Withdrawn

**(1) Sorenson Does Not Anticipate Or
Render Obvious the Pending Claims**

Claims 1, 3-8 and 16-20 have been rejected under 35 U.S.C. § 102(b), as anticipated by U.S. Patent Publication No. 2002/0020665 by Kent S. Sorenson ("Sorenson") or, in the alternative, under 35 U.S.C. § 103(a), as obvious over Sorenson in combination with an abstract by J. He and F. Loffler, "Isolation Of a Vinyl Chloride-Respiring Population In Pure Culture," *Abstracts of the General Meeting of the American Society for Microbiology* (May 18-22, 2003) Vol. 103, pp. Q-016 (the "He Abstract").

According to the Official Action:

Sorenson teaches Dehalococcoides isolate for remediating a substrate comprising a halogenated compound which includes dichloroethene (DCE), and cis-DCE, vinyl-halide, including vinyl-chloride.

See in the Official Action at page 6, *citing* Sorenson at page 2, ¶ [0010] and at page 3, ¶ [0025]. However, Sorenson actually describes a bioremediation method where an electron donor composition, such as lactose, is added to contaminated ground water. According to Sorenson, halo-respiring microbes *already in the ground water* will then reductively dehalogenate contaminating solvents. See Sorenson at ¶ [0025], lines 1-10. Sorenson also states that “[i]f halo-respiring microbes are absent or ineffective, then such microbes can be exogenously supplied to the ground water.” *Id.* at ¶ [0025]. However, Sorenson teaches only two microbes for this: (1) *Dehalococcoides ethenogenes* strain 195, and (2) the Pinellas culture. *Id.*; *see also* Sorenson at ¶ [0047].

The *Dehalococcoides ethenogenes* strain 195 that Sorenson mentions is not capable of using *either* *trans*-DCE or vinyl chloride as a metabolic electron acceptor. In particular, the Examiner’s attention is respectfully directed to the publication of Maymó-Gatell *et al.*, “Reductive Dechlorination of Chlorinated Ethenes and 1,2-Dichloroethane by ‘*Dehalococcoides ethenogenes*’ 195” *Appl. Environ. Microbiol.* (1999) 65(7):3108-3113 (Maymó-Gatell), which was submitted with Applicant’s Supplemental Information Disclosure Statement filed July 3, 2008. The Maymó-Gatell publication describes experiments characterizing the *Dehalococcoides ethenogenes* strain 195 mentioned by Sorenson, and concludes that “neither *trans*-DCE nor VC [vinyl chloride] could serve as an electron acceptor for growth of strain 195.” *See* Maymó-Gatell at page 3112, lines 3-5 of the left-hand column.

With respect to the Pinellas culture, Sorenson teaches that it is described in two publications: (i) M.R. Harkness *et al.*, “Use of Bioaugmentation to Stimulate Complete Reductive Dechlorination of Trichloroethene in Dover Soil Columns,” *Environmental Sci. Technol.* (1999) 33:1100-1109 (“Harkness”); and (ii) D.E. Ellis *et al.*, “Bioaugmentation for Accelerated *In Situ* Anaerobic Bioremediation,” *Environmental Sci. Technol.* (2000) 34:2254-2260 (“Ellis”). Copies of both these publications are provided with the Third Information Disclosure Statement accompanying this Response. Harkness teaches that the Pinellas culture is an enriched culture of microorganisms from soil samples. *See* Harkness at 1102, left-hand column (“Development of the Pinellas Culture”). Harkness also describes microbial

characterization of this culture, and teaches that DNA sequences were isolated from a variety of microorganism species in the culture. *Id.* at 1102, right-hand column. Ellis states that the Pinellas culture is “[a] crude enrichment suspended culture isolated from the Department of Energy’s (DOE’s) Pinellas site in Largo, FL.” *Ellis* at 2255, right-hand column. Ellis also states that molecular characterization of the culture “showed the presence of *Dehalococcoides ethenogenes*.” *Id.* at 2257, right-hand column. However, there is no teaching or suggesting that these *Dehalococcoides ethenogenes* can use either *trans*-DCE or vinyl chloride as a metabolic electron acceptor. Moreover, Ellis states that “the abundance of this organism [*Dehalococcoides ethenogenes*] was low relative to other phylogenetic types” found in the culture. *Id.* Hence, the Pinellas culture is not a biologically pure bacterial culture, let alone a biologically pure culture comprising *Dehalococcoides* isolate that uses either *trans*-DCE or vinyl chloride as an electron acceptor.

Anticipation requires each and every element of the rejected claim(s) must be disclosed in a single prior art reference. M.P.E.P. § 231. “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). As explained above, neither Sorenson nor any of the publications cited therein describes a “biologically pure *Dehalococcoides* isolate” that is capable of using either *trans*-DCE or vinyl chloride as a metabolic electron acceptor. Sorenson cannot, therefore, anticipate Applicant’s pending claims.

With respect to the He Abstract, Applicant respectfully points out that it is an article describing the inventor’s own work, which published less than one year before the priority date of this application. The He Abstract is not, therefore, available as “prior art” against this application or its pending claims. This is explained in detail below.

For all of the foregoing reasons, Applicant submits that the rejection under 35 U.S.C. § 102(b) for anticipation by the Sorenson publication, and the rejection under 35 U.S.C. § 103(a) for obviousness over Sorenson and He should be withdrawn. Sorenson does not describe a

“biologically pure” *Dehalococcoides* isolate that is capable of using either *trans*-DCE or vinyl chloride as a metabolic electron acceptor, as recited in the pending claims. It cannot, therefore, anticipate those claims. The He Abstract is not available as prior art, and so cannot be used to reject Applicant’s pending claims for obviousness. Applicant therefore respectfully requests that the rejections under 35 U.S.C. § 102(b) and § 103(a) over Sorenson be withdrawn.

(2) The He Abstract Is Not Available As “Prior Art”

Pending claims 2 and 9-15 have also been rejected under 35 U.S.C. § 102(a) as anticipated by the He Abstract. Applicant respectfully traverses this rejection and requests reconsideration by the Examiner. While the He Abstract may state that “[a]n anaerobic VC-respiring population, designated as strain BAV1, was isolated” and that “gene sequencing placed the isolate in the Pinellas group within the *Dehalococcoides* cluster,” the abstract does not describe a reproducible means by which a person skilled in the art might obtain that isolate. Nor does the He Abstract make its isolate available to the public, *e.g.*, by providing a microorganism deposit. Hence, the He Abstract does not provide an enabling disclosure of its BAV1 isolate. “The disclosure in an assertedly anticipating reference must provide an enabling disclosure of the desired subject matter; mere naming or description of the subject matter is insufficient, if it cannot be produced without undue experimentation.” M.P.E.P. § 2121.01, *citing Elan Pharm., Inc. v. Mayo Found. For Med. Educ. & Research*, 346 F.3d 1051, 1054, 68 U.S.P.Q.2d 1373, 1376 (Fed. Cir. 2003). For this reason alone, the rejections over the He Abstract are improper and should be withdrawn.

In addition, Applicant respectfully points out that the He Abstract is an article describing the inventor’s own work, which published less than one year before the priority date of this application. The He Abstract is not, therefore, available as “prior art” against this application or its pending claims. In this regard, the Examiner’s attention is respectfully directed to the accompanying Declaration of Prof. Frank Loeffler, Ph.D. (the “Loeffler Decl.”). Prof. Loeffler, who is the sole inventor of this application, explains that the He Abstract is an article co-authored by him and his student, Jianzhong He. *Loeffler Decl.*, ¶ 4. According to Prof. Loeffler, the Abstract was publicly presented on or about May 18, 2003 (*Id.*); less than one

month before this application's priority date of June 10, 2003.¹ Prof. Loeffler also explains that Dr. He's contribution to the work described in the He Abstract was to perform experiments under Prof. Loeffler's supervision and control. *Loeffler Decl.*, ¶ 6. Dr. He did not, therefore, make an inventive contribution to the work described in the He Abstract.

A rejection based on a publication may be overcome by showing that the publication was either by the Applicant himself or made on his behalf, unless the publication is a statutory bar. MPEP § 715.01(c). In the present situation, where the inventor is a co-author of the publication, published less than one year prior to the priority date of the application, the rejection may be overcome by filing an affidavit or declaration under 37 CFR § 1.132 establishing that the article is describing the inventors' own work. An affidavit or declaration by the inventor alone, indicating that he is the sole inventor and that the other co-author was merely working under his direction is sufficient to remove such a publication as a reference under 35 U.S.C. § 102(a). MPEP §715.01(c)(I), citing *In re Katz*, 687, F.2d 450, 215 USPQ 14 (CCPA 1982).

Since the He Abstract published less than one year before this application's priority date, it could only be prior art against this application, if at all, under 35 U.S.C. § 102(a). It is not a statutory bar. Prof. Loeffler's Declaration establishes that the He Abstract describes his own work, and that the abstract's co-author, Jianzhong He, was merely working under his direction. Hence, the He Abstract is not available as "prior art" against this application.

In view of the foregoing, Applicant respectfully submits that the rejections for anticipation and/or obviousness over the He Abstract should be withdrawn.

C. Conclusion

For all of the foregoing reasons, it is believed that each basis for rejection of and objection to this application and its pending claims has been overcome and/or obviated. The entry and consideration of these amendments, withdrawal of all rejections and objections and

¹ This application is the U.S. national phase of an International patent application (No. PCT/US04/19000) filed on June 10, 2004. However, it claims priority to a provisional application (Serial No. 60/477,799) filed on June 10, 2003, and is entitled to that provisional application's early filing date.

allowance of the application are therefore all respectfully requested. The Examiner is invited to contact Applicant's undersigned representatives should she conclude that there are any remaining issues that could be resolved, *e.g.*, by either a Supplemental Response or an Examiner's Amendment. An allowance is earnestly sought.

Respectfully submitted,

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